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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/670,421	09/26/2000	Dale Wallis	40224.00001	5703
30983	7590	03/08/2004	EXAMINER	
MCDONOUGH, HOLLAND & ALLEN 555 CAPITAL MALL 9TH FLOOR SACRAMENTO, CA 95814			NAVARRO, ALBERT MARK	
			ART UNIT	PAPER NUMBER
			1645	

DATE MAILED: 03/08/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

SM

Office Action Summary	Application No. 09/670,421	Applicant(s) WALLIS ET AL.	
	Examiner Mark Navarro	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-17, 19, 20, 24, 27 and 28 is/are pending in the application.
 4a) Of the above claim(s) 12-17 and 19 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 20, 24, 27 and 28 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

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DETAILED ACTION

Applicants amendment filed December 1, 2003 has been received and entered. Claims 18, 21-23, and 25-26 have been canceled and new claims 27-28 have been added. Consequently claims 12-17, 19-20, 24, and 27-28 are pending in the instant application, of which claims 12-17 and 19 have been withdrawn from further consideration as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 112

1. The rejection of claim 18 under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a pharmaceutical composition of Serpens strain HBL-112, does not reasonably provide enablement for all pharmaceutical compositions of Serpens, immunologically active portions thereof, and antigenic eptiopes cross-reactive with the Serpens genera is withdrawn in view of the cancellation of said claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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2. The rejection of claims 20 and 24 under 35 U.S.C. 102(b) as being anticipated by Hespell is maintained. Additionally this rejection is applied to newly added claims 27-28.

Applicants are asserting that Hespell does not disclose a “veterinarily acceptable diluent or carrier element.” Applicants agree that Hespell discloses culturing *Serpens flexibilis* in a lactate broth which contains distilled water, but that lactate broth is not a veterinarily acceptable diluent or carrier. Applicants further assert that claim 24 has been further amended to refer to “killed” bacteria of the genus *Serpens* rather than attenuated bacteria, and that Hespell does not teach an “attenuated” or “killed” bacteria of the genus *Serpens*.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants assert that Hespell does not disclose a “veterinarily acceptable diluent or carrier element.” However, distilled water, present in the composition disclosed by Hespell, is a “veterinarily acceptable diluent.” (See, for example, US Patent Number 3,673,205, column 3, lines 71-73). The mere fact that additional ingredients are present above and beyond those recited in the claims does not detract from the disclosed composition teaching each and every limitation of the claims. Applicants transitional phrase of “An immunogenic composition **comprising...**” (Emphasis added) allows for additional elements to be present.

Second, Applicants assert that claim 24 has been further amended to refer to “killed” bacteria of the genus *Serpens* rather than attenuated bacteria, and that Hespell

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does not teach an “attenuated” or “killed” bacteria of the genus *Serpens*. However, Applicants are respectfully directed back to the claims. The claims encompass “killed bacteria belonging to the genus *Serpens* and an immunologically active portion of killed bacteria belonging to the genus *Serpens*.” Those of ordinary skill in the art would recognize that not every single *Serpens* microorganism in the culture composition disclosed by Hespell would have been alive. While the number of living microorganisms were certainly increasing in the culture, many of the microorganisms would also be dead. Consequently, the presence of a certain amount of inherent “dead” microorganisms is sufficient to address each and every limitation of the claimed invention. Furthermore, Applicants claims recite “immunologically active portions of killed bacteria belonging to the genus *Serpens*.” Immunologically active portions certainly include numerous proteins of undefined structure and activity, and even small peptide epitopes of proteins. How exactly would one “kill” an immunologically active portion? In other words, the immunologically active portions would have the identical structure in both live and killed bacteria. As such the recitation of “immunologically active portion” of a “killed” bacteria does not distinguish over the prior art, given that the compositions would contain the identical structures regardless of if the “immunologically active portion” was isolated from a live or killed *Serpens*.

Finally, Applicants have added new claims 27-28, reciting that the immunogenic composition further comprises an adjuvant. However, the composition disclosed by Hespell contains lactate. As those of skill in the art would recognize, lactate is an

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adjuvant. (See for example US Patent 4,587,254, column 4). Again, Hespell discloses of each and every claim limitation.

The claims are drawn to an immunogenic composition comprising an immunologically effective amount of at least one member selected from the group consisting of bacteria belonging to the genus *Serpens* and an immunologically active portion of bacteria belonging to the genus *Serpens* and a veterinarily acceptable diluent or carrier.

Hespell (International Journal of Systematic Bacteriology Vol. 27, No. 4, pp 371-381, October 1977) disclose of isolated *Serpens flexibilis*. Hespell further discloses of culturing *Serpens flexibilis* in a lactate broth which contains 100ml of distilled water.

In view that Hespell discloses of an isolated *Serpens flexibilis* in combination with a veterinarily acceptable diluent (distilled water), the disclosure of Hespell is deemed to anticipate the claimed invention.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

Claim Rejections - 35 USC § 112

3. The rejection of claims 21-23 and 25-26 under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time

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the application was filed, had possession of the claimed invention is withdrawn in view of the cancellation of said claims.

4. The rejection of claims 20 and 24 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is maintained. Additionally this rejection is applied to newly added claims 27-28.

Applicants are asserting that the specification discloses two members of the genus, *Serpens* spp. HBL-112 and *Serpens flexibilis*, both of which will function as part of an immunogenic composition. Applicants further assert that the characteristics of these species, which are thoroughly described in the text and tables of the specification, adequately represent the characteristics of the genus, such that one of ordinary skill in the molecular biological arts would be able to identify another member of the species. Applicants finally assert that the immunological composition claims include as a limitation the bacterial species of the *Serpens* genus.

Applicants arguments have been fully considered but are not found to be fully persuasive.

First, Applicants are asserting that the specification discloses two members of the genus, *Serpens* spp. HBL-112 and *Serpens flexibilis*, both of which will function as part of an immunogenic composition. However, Applicants are respectfully directed to their own specification. For instance, *Serpens* spp. HBL-112 is found to be negative for the Voges-Proskauer test, a test for the production of acetylmethylcarbinol from glucose in bacterial cultures, while *Serpens flexibilis* is found to be positive for the same test.

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Furthermore, *S. flexibilis* is capable of reducing nitrite to nitrogen, whereas *Serpens* spp HBL-112 is not. Consequently, Applicants disclosure of two species with different properties is simply not commensurate in scope with the genus claim language given that the two species have distinct structures and activities.

Vas-Cath Inc. V. Mahurkar, 19 USPQ2d 111, clearly states that “applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed.” The specification does not “clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.”

Applicant is reminded that Vas-Cath make clear that the written description provision of 35 USC 112 is severable from its enablement provision.

Finally, Applicants assert that the immunological composition claims include as a limitation the bacterial species of the *Serpens* genus. However, as set forth above, Applicants description of two species, with different characteristics, does not allow those of skill to identify members of the genus. Furthermore, Applicants claims encompass “immunologically active portions.” Applicants specification has not set forth of the structure or activity of any of these portions. Adequate written description requires more than a mere statement that it is part of the invention and a reference to a potential method of isolating it. The protein itself is required. See *Fiers v. Revel*, 25 USPQ 2d 1601 at 1606 (CAFC 1993) and *Amgen Inc. v. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016.

For reasons of record, as well as the reasons set forth above, this rejection is maintained.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro whose telephone number is (571) 272-0861. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark Navarro
Primary Examiner
March 4, 2004